

CONFIDENTIAL

# **fishPHARM**

## **Summary Business Plan**

Prepared August 2015

### **Contact Information**

George Danias  
gd266@cornell.edu

## **Table of Contents**

(will be written for final draft)

## **Executive Summary**

(will be written for final draft)

## **Industry Analysis**

Our general industry is the aquaculture industry, with a focus on the aquaculture pharmaceutical industry.

As of 2010, the global aquaculture market produced 80 million tons of seafood, with a total value of \$86 billion dollars. It has also grown at about 8% annually for the past 30 years. However, both size and growth rate figures have a degree of uncertainty due to documented over-reporting from the world's largest producer, China.

Since aquaculture is a fairly new industry, only appearing in the past 40 years, it is quite fragmented. Several hundred companies exist around the globe producing many different types of products. For salmon, 15 companies account for 70% of production capacity. However, these numbers do not necessarily indicate a competitive market, since the majority of aquaculture companies are regional. A number of organizations, like the Global Aquaculture Alliance and Global Salmon Initiative, exist, making it easy to reach numerous firms. Another consequence of the industry's youth is that it is quite susceptible to change and innovation. A myriad of new technologies are used by fish farms, since no method thus far has been without its issues.

Wild fisheries around the world are in decline, due to the degeneration of many types of natural habitats. While one would expect this to boost the aquaculture industry, many types of fish are piscivorous (eat other fish), and the loss of natural habitats severely constrains the supply of food. Salmon farming has actually been shown to have negative impacts on wild salmon due to the sheer amount of food used and poor management of pollution. Therefore, the adaption of sustainable practices is crucial to the long term prospects of the industry.

Thankfully, several new management techniques exist as well as technology like fallowing netpens, recirculating systems, and Integrated Pest Management Vaccines. Products like flavocide and fishBIT can even be beneficial to sustainable practice, since they reduce antibiotic use for disease control. However, of the major aquaculture techniques used for production in the US, newer sustainable technologies only make up about 25% of total production capacity, according to the 2013 USDA Census of Aquaculture. Since the United States is not even in the top 10 producers of farmed fish in the world, its sustainable production capacity is insignificant. China accounts for 61% of global production, while other Asian countries account for much of the remainder. Regulations of aquaculture in many of these countries often don't exist, are poorly traced, or lack proper enforcement. This adds a large amount of uncertainty to the future of the aquaculture industry unless a global initiative arises to address the issues it faces. Despite these challenges, we believe that aquaculture will expand in years to come to respond to a growing population.

## **Company Description**

fishPHARM was conceived in the summer of 2015 by members of the Cornell iGEM biological engineering project team. The company would combine the academic endeavors of the 2015 project (combating bacterial cold water disease on fish farms using biologically engineered and harvested peptides as an alternative to antibiotics, delivering these peptides to the fish using biomedically engineered drug delivery devices, and creating a cheap and accessible farm monitoring system for disease prevention). FishPHARM would develop these technologies into marketable products for the fish farmers of the world, as to make their farms more sustainable, environmentally responsible, and cost-effective.

### **Mission Statement**

We at FishPHARM believe sustainable, environmentally responsible, and efficient aquaculture is one of the best ways of providing a growing global population with the food it needs to thrive. We also believe that overuse of antibiotics on today's fish farms is detrimental to both the consumer and the aquaculture industry, and that outbreaks of bacterial cold water disease (BCWD) and lack of efficient preventative monitoring systems are real issues that affect the productivity of today's fish farmers. We at fishPHARM make it our mission to produce antibiotic-free treatments for BCWD, design and manufacture effective and safe drug delivery methods for aquacultured fish, and design and manufacture farm monitoring systems for the purpose of disease prevention and general fish well-being. With these initiatives, fishPHARM will help aquaculture around the globe attain a more sustainable position for food production.

### **Products and Services**

FishPHARM produces three main products:

1. Flavocide: A peptide treatment for BCWD

Flavocide is an isolated laboratory-purified entericidin protein obtained from genetically modified E.Coli. Entericidin poses very little to no health risks to humans and fish, and specifically targets the etiological agent of bacterial cold water disease, an organism called flavobacterium. The protein is contained at an x% weight in a common gel material poly(lactic-co-glycolic acid), or PLGA, which naturally degrades in liquid solutions to release entericidin into the desired system. PLGA poses no risk to biological systems according to the FDA.

2. fishBIT: A drug delivery system for Flavocide for long-term release

fishBIT is a drug delivery system for Flavocide gel. It is inspired by the existing practice of tagging fish for research purposes. The original fish tag design has been modified to store a specified dosage of Flavocide and expose it to the fish systemically over a certain amount of time. It is administered on an individual basis. The entire system also includes an applicator, which is used to inset fishBIT into the fish body.

3. Heimdall Monitoring System (HMS): A prototype tank monitoring system, consisting of a temperature sensor and a flow rate sensor, as well as a mobile app for remote monitoring.

The HMS is in a very early stage of development. It is an Arduino based system for monitoring the temperature and flow rate of an aquaculture tank. It

communicates with a mobile app to bring live data to the user. More functions for Heimdall are being developed.

Current Status

FishPHARM has not been incorporated yet. Our team is in the process of legally starting the company. When the company is officially started, it will be owned by Cornell University and by founding members on the Cornell iGEM project team. The following members will hold 26% of the non-Cornell owned stock: George Danias, Jonlin Chen, and Michelle Zhang. The remaining 22% of non-Cornell owned stock will be divided equally among team members Neema Patel, Rishabh Singh, Yi Fan Chen, and Eric Holmes.

Key Partnerships

FishPHARM will continue to maintain relationships with all of its corporate sponsors, Cornell University, and Cornell faculty as well as it can. These partnerships will provide consulting and logistical assistance

Market Analysis

Market Segmentation

Organizational/ Demographic	Geographic	Psychographic	Behavioral
<ul style="list-style-type: none"><li>• Individual farmers - more fragmented, but more manageable scale initially</li><li>• Aquaculture companies - larger scale, larger impact</li></ul>	<ul style="list-style-type: none"><li>• US market - Significantly smaller, but more accessible, more regulation</li><li>• International (mostly South and East Asian) market - much larger, but less accessible</li></ul>	<ul style="list-style-type: none"><li>• Farmers looking for new solutions to BCWD - value sustainability and efficacy of treatment</li><li>• Farmers satisfied with antibiotic treatment - value ease of use (no individual tagging)</li></ul>	<ul style="list-style-type: none"><li>• First-time users - never used fish tags for other purposes</li><li>• Regulars - use fish tags for population tracking, etc.</li><li>• Ready to try</li><li>• Skeptical</li></ul>

## **Buyer Behavior**

The desired outcome for fish farmers is that their salmon remain unaffected by BCWD. Currently, antibiotic treatments combined with proper monitoring and use of hydrogen peroxide can keep incidence rates low in most fish farms. However, during outbreaks, affected fish can have high mortality rates. Antibiotic treatments can work well, but may eventually be self-defeating and more costly if resistance develops. Individual farmers are likely to be low-middle income and may not be concerned with the other environmental risks associated with antibiotic treatment. Because of these reasons, antibiotic overuse is common, despite constant reminders from supervisors to avoid them.

Ultimately, the willingness of a farmer to buy the fishPHARM product depends on the number of fish affected versus the cost of the system. A well maintained farm can potentially buy a small number of tags as a measure to control an outbreak in its early stages. A farm experiencing an outbreak may buy a large number, depending on the cost of the measure. If antibiotics or hydrogen peroxide can stop the spread, and the number of fish affected is small enough to be written off, farmers may not buy the product altogether.

## **Competitor Analysis**

There are currently no direct competitors in this market. No similar type of treatment exists for BCWD.

The only indirect competitors are the pharmaceutical companies producing the antibiotics, since they address the same need, but in a different way. Antibiotics are effective, but can lead to bacterial resistance (a costly and potentially devastating problem in the future). FishPHARM provides a potentially more effective treatment with no chance for resistance, but this treatment is more difficult to administer on a large scale. Indirectly competing, fish treated with antibiotics will fare worse in market against antibiotic-free fish, since there is a stigma against using antibiotics in food production. This may provide an incentive for farmers to ditch antibiotics as a treatment.

Future competitors can arise very quickly if no patent is acquired on fishBIT or Flavocide. Both of these technologies are not difficult to replicate and a player with more market force can potentially outcompete fishPHARM by scale alone. Another future competitor is a vaccine for BCWD – currently in development – but its effectiveness is currently unknown.

## **Economy of the Business**

### **Start Up Costs**

Currently, the total start-up cost of our business is estimated to be around \$110,000. This is likely to be an overestimation of the actual start-up cost.

The total start-up cost is based on the assumption that it will take one year until the first successful sale of our product, and that we lack access to a means of mass production to lower average total cost of production. We therefore estimate the cost of production of 1,000 fish tag



kits to be around \$15,640. Much of the start-up cost can be attributed to land and capital (\$24,500 and \$20,000, respectively). The remaining components of the start-up cost can be attributed to legal fees and marketing.

\$30,000 is reserved for contingencies. Although this amount is not based on any supporting statistics due to the lack of similar competing businesses, we nevertheless believe this to be a reasonable quantity.

## **Revenue Drivers**

Our company is centered on four main revenue drivers: Flavocide gel, fishBIT tags, fishBIT applicators, and the Heimdall Monitoring System. Flavocide and fishBIT tags will be the primary revenue streams. These two products will need to be occasionally replenished by fish farmers as new outbreaks emerge. The third most lucrative revenue driver will be the Heimdall Monitoring system, once it is marketable. If this sensor device and mobile app are installed at every fish farm in the US, this product will bring in a fair amount of revenue. Finally, the fishBIT applicator will be the final revenue stream. While a farm's first set of fishBIT tags will include one or two free applicators, farms can purchase additional applicators.

## **Marketing Plan**

### **Overall Marketing Strategy**

FishPHARM will begin its business by only focusing on sales of the fishBIT and flavocide treatment for BCWD. Therefore, it will need to persuade farmers to treat their fish without the use of antibiotics. Extensive research will be done on the drug and on the delivery system, and

this information will be sent in packets to individual farmers. Farmers will have the option of ordering a free starter kit of the treatment, consisting of 20 fishBIT tags, a fishBIT applicator, a 5mL vial of Flavocide, and an instruction manual. Hopefully, these two methods will allow fishPHARM to gain a foothold in the aquaculture market. Advertisements will also be distributed online, in trade journals, and at trade shows to further promote the brand.

### **Product Distribution**

The starter kits will contain 20 fishBIT tags. These will be free and can be ordered online by fish farmers. Large quantities of tags and Flavocide will be offered for farmers that wish to switch to fishPHARM. Considering that fishPharm is based in New York State, there will be fixed standard rate for the Northeast region of the US. Other regions will have shipping fee dependent on distance. Products will be distributed using major mail carriers in climate controlled packages.

### **Sale Process & Tactics**

All products will be ordered and sold online.

## **Design and Development Plan**

### **Development status**

FishBIT was designed using 3D computer design software. It is ready for small-scale production using 3D printing. The fishBIT applicators are being machined using lathes and are also available for small-scale production. The progress on Flavocide is slower; we are currently

expressing proteins and testing their efficacy while simultaneously optimizing our protocols.

However, once we have ascertained the most effective protein, we will have the means of purifying these proteins in large quantities. The Heimdall Monitoring System is still in its design phase, but will be ready for more advanced prototyping by the end of 2015.

## **Challenges**

While we are unaware of any major problems with our design, some may arise when we begin to test our products in the real world. The fishBIT tag may need modifications to adequately remain in the fish it is administered to, or to deliver the drug properly. Our Flavocide gel recipe will have to be designed as to provide adequate dosing in the correct amount of time. We will address these issues by conducting a rigorous testing process on all of our products. Another problem that may arise is the cost of manufacturing our products. We have not yet focused on optimizing the costs of production. Designing a method of mass production of each of our products will be necessary to drive costs down.

## **Intellectual Property**

We are currently in the process of obtaining patenting rights through Cornell University's Center for Technology Licensing.

## **Management Team and Company Structure**

### **Management Team**

The company will be led by the following three individuals upon foundation:

1. Jonlin Chen

Chief Operations Officer

Extensive research and biotechnology experience

Attends Cornell University

2. George Danias

Chief Executive Officer

Extensive research and engineering experience

Attends Cornell University

3. Michelle Zhang

Chief Technical Officer

Extensive research and biotechnology experience

Attends Cornell University

## **Company Structure**

The following list demonstrates the company structure fishPHARM will assume upon foundation:

- Board of Directors (Including CEO, COO, CTO)
  - Finance (Pays taxes, manages capital and costs)
  - Human Resources (Recruiting, payroll)
  - Research and Development
    - Biology Division (Drug development, clinical trials)

- Engineering Division (Delivery system design and optimization, product trials)
- Manufacturing
  - Pharmaceutical Division (Large scale drug production, gel suspension)
  - Delivery Division (Large scale drug delivery system manufacture)
  - Monitoring Division (Large scale production of monitoring systems)
  - Packaging Division (Large scale production of product packaging)
- Information Technology (Modeling, software development, app development, website maintenance)
- Marketing (Identify new markets, advertise products, community outreach, public relations)

## Overall Schedule

The following timeline represents our overall schedule:

September 24 <sup>th</sup> , 2015	iGEM international competition presentation
November 2015	Injection-mold design of fishBIT tag
	Order tubing for more efficient applicator production
	Finalize Flavocide gel recipe
	Extensive laboratory testing
December 2015	Apply for patents
	Apply for copyrights
	Finalize sensor design
January 2015	Legally establish fishPHARM
	Begin clinical trial application process